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Payment for Positron Emission Tomography Scans in CMS-Approved Clinical Trials and Coverage with Evidence Development - Use of QR and QV Modifiers

Key Words

MM5124, CR5124, R956CP, FDG, PET, Tomography, Scans, Modifier, Code, Registry, R31NCD, R527CP, MM3741, Oncology, Dementia, Neurodegenerative

Provider Types Affected

Physicians and other providers who bill Medicare carriers and fiscal intermediaries (FI) for the use of FDG PET scans for oncology and dementia/neurodegenerative diseases

Key Points

- The effective date of the instruction is January 28, 2005.
- The implementation date is June 19, 2006.

Positron Emission Tomography (PET)

- Positron emission tomography (PET) is a noninvasive imaging procedure that assesses perfusion and the level of metabolic activity in various organ systems of the human body.
- A positron camera (tomograph) is used to produce cross-sectional tomographic images obtained by detecting radioactivity from a radioactive tracer substance (radionuclide), 2-[F-18] Fluoro-D-Glucose (FDG).
- Publication 100-03, the *National Coverage Determinations (NCD) Manual*, Section 220.6, provides coverage instructions that indicate conditions under which a PET scan is performed. The manual is available at http://www.cms.hhs.gov/Manuals/IOM/list.asp#TopOfPage on the Centers for Medicare & Medicaid Services (CMS) web site.

Covered FDG PET Scans

- For cancers listed as “coverage with evidence development” in Section 220.6 of the *NCD Manual,* CMS has determined that (effective for services performed on or after January 28, 2005) FDG PET scans are reasonable and necessary only when the provider is participating in, and patients are enrolled in:

  - A clinical trial that meets the requirements of Food and Drug Administration (FDA) category B investigational device exemption (42 CFR 405.201); or
  - An FDG PET clinical study that is designed to collect additional information at the time of the scan to assist in patient management.
- CR3741, released April 15, 2005, indicated that there is adequate evidence to conclude that an FDG PET scan for the detection of pre-treatment metastases (i.e., staging) in newly-diagnosed cervical cancer (after conventional imaging that is negative for extra-pelvic metastasis), is reasonable and necessary as an adjunct test, and it expanded coverage to include FDG PET for certain indications of cervical cancer.
- CR3741 also designated QV as the correct modifier to be used in carrier claims for beneficiaries participating in CMS-approved clinical trials utilizing FDG PET scans for dementia and neurodegenerative diseases.
- CR5124, upon which MM5124 is based, revises CR3741 to provide that (effective for services on or after January 28, 2005) providers will be reimbursed for the use of FDG PET services for:
  - Dementia and neurodegenerative disease (see NCD Manual (100.03) section 220.6.13);
  - Certain indications for cancers of the cervix, lung (including small cell), esophagus, colon and rectum, head and neck, breast, thyroid, brain, ovary, pancreas, and testes; and lymphoma, melanoma, and soft tissue sarcoma (as listed in sections 220.6.2-220.6.7 and 220.6.10-220.6.14); and
  - All other cancer indications not previously specified (as listed in section 220.6.15);
  - Only if these scans were performed as part of a CMS-approved clinical trial.
- Providers should be aware that FDG PET scans for all cancer indications listed in section 220.6 as "coverage with evidence development" remain nationally non-covered unless they are performed in conjunction with a CMS-approved clinical trial.

Using Appropriate CPT Code and QR Modifier

- In line with the requirement for including these patients in clinical trials, providers must submit all (other than inpatient) FDG PET claims to their carriers using the appropriate CPT code and the QR modifier, which was created for use on Part B claims (and other outpatient claims) to identify items/services that are covered when provided in a Medicare-specified study.
- The QV modifier may no longer be used when a beneficiary undergoes an FDG PET scan in a facility participating in a Medicare-approved study specified by the above-referenced NCDs.

National Oncologic PET Registry (NOPR)

- Providers should also be aware that CMS contracted with the Academy of Molecular Imaging (AMI) to establish the NOPR, a national, internet-based data registry that reports on oncologic FDG PET scans received by Medicare beneficiaries as outlined in the NCD.
- Reporting data to the NOPR for the oncologic FDG PET scan indications listed in section 220.6 as "coverage with evidence development" is a requirement of Medicare coverage. Without appropriately

reported data, Medicare may be unable to approve claims and/or may be required to take action to recoup payments already made if data reporting discrepancies are discovered through post-payment claims analysis.

- Providers are responsible for ensuring that data is accurately reported to the NOPR and that claims are accurately submitted.
- CMS recommends that providers contact NOPR so that their facility may provide expanded oncologic FDG PET benefits under the NCD.
- When submitting such claims to their FIs, providers should use the appropriate principal diagnosis code, the appropriate CPT code, and ICD-9 code V70.7 in the second diagnosis position on the CMS-1450 (UB-92), or the electronic equivalent.
- Effective for PET scan claims with dates of service on or after January 28, 2005, until implementation of CR5124 on June 19, 2006, carriers and FIs do not need to search their files to either retract erroneous payment for claims already paid or to retroactively pay claims incorrectly processed, unless providers bring those claims to their attention.

Important Links

http://www.cms.hhs.gov/MLNMattersArticles/downloads/mm5124.pdf

- More information about FDG PET scans in patients undergoing Medicare approved clinical trials may be found by going to CR5124, located at http://www.cms.hhs.gov/Transmittals/downloads/R956CP.pdf on the CMS web site.
- Additionally, providers might want to look at the *National Coverage Determinations (NCD) Manual*, sections 220.6, 220.6.2 - 220.6.7, 220.6.10 - 220.6.12, 220.6.14, and 220.6.15 for important information regarding FDG PET for oncology. The transmittal that conveyed the above NCD is available at http://www.cms.hhs.gov/Transmittals/downloads/R31NCD.pdf on the CMS web site.
- A related Medicare Claims Processing Manual transmittal is available at http://www.cms.hhs.gov/Transmittals/downloads/R527CP.pdf on the CMS web site.
- A related MLN Matters article appears at http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3741.pdf on the CMS web site.
- Information and registration materials are available at NOPR's web site: http://www.cancerPETregistry.org.
- A regularly updated list of NOPR's Medicare approved facilities is located at http://www.cms.hhs.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage on the CMS web site.